REMARKS

The present application is directed to methods and a kit for detecting animal byproducts in samples. The method and kits are particularly useful in the detection of animal byproducts in feed, such as animal byproducts rendered in meat and bone meal. Detection of animal byproducts in feed is useful for reducing transmission of pathogens such as those causing mad cow disease.

Claims 1-16 were pending prior to the issuance of the September 10, 2004, Non-Final Office Action. Following entry of this amendment Claims 1-8, and 10-21 will be pending. Claims 14 and 16 are withdrawn, and Claim 9 is cancelled. Claims 1-4 are currently amended. New Claims 17-21 have been added. No new matter is added and support for the amendments is found throughout the specification and in the original claims.

Confirmation of Election/restriction requirement

Pursuant to the telephonic discussion with the Examiner on August 23, 2004 regarding a Restriction Requirement, applicants confirm the election of Group I, Claims 1-13 and 15, drawn to a method and a kit for performing the method.

***Claim rejections 35 U.S.C. §112* second paragraph**

In the September 10, 2004 Non-Final Office Action, the Examiner rejected Claims 1-13 and 15 under 35 U.S.C. §112, second paragraph, as indefinite on the basis that the body of the claim lacked a preamble, it was unclear to what the method was directed, and it was unclear how the complex could be determined without a detectable label. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Applicants have amended Claim 1 to clarify that the method detects rendered animal byproduct in a sample, the ligand is detectable, and the unbound ligand is separated from the complex. Applicants respectfully submit that the conditions and length of time required to form a complex, as recited in Claim 1, will be understood by those skilled in the

art. (see page 17, lines 15-26). Applicants respectfully submit that they have overcome the Examiner's rejection under 35 U.S.C. §112, second paragraph, and request withdrawal thereof.

Claim rejections 35 U.S.C. §102 (b)

In the Non-Final Office Action mailed September 10, 2004, the Examiner rejected Claims 1, 2, 6 and 8 under 35 U.S.C. §102(b), as anticipated by the article of Ansfield (*Food & Agricultural Immunology* 6:419-433, 1994) (hereinafter the "Ansfield article"). Applicants respectfully submit that the amendments to the Claims overcome the rejection.

The Ansfield article discloses a pretreatment method in an immunoassay for the detection of bovine and ovine ruminant proteins in rendered animal materials. The Ansfield article teaches that gelatin must first be removed from the test sample because of its ability to depress enzyme immunoassay sensitivity (see page 419, last two lines). In the Ansfield article, the sample is pretreated by removing the gelatin via ammonium sulfate precipitation.

Claim 1 has been amended to specify that the sample is animal feed or a component thereof, that the unbound ligand is removed from the complex, and that the amount of rendered animal byproduct detected is about 0.005% to about 0.5% by weight. In addition, the present method does not require the removal of gelatin from the sample prior to analysis. Similarly, the present method does not require concentration of proteins in the sample prior to testing. Clearly, the pretreatment method of the Ansfield article and the method utilized in the present application are quite different, with the Ansfield article requiring at least two additional method steps. The sensitivity of the method of the present application allows for the detection of low amounts of animal byproduct in an animal feed sample without a concentration procedure. Accordingly, Applicants respectfully submit they

have overcome the Examiner's rejection under 35 U.S.C. §102(b) and request withdrawal thereof.

In the September 10, 2004, Non-Final Office Action, the Examiner rejected Claims 1, 2 and 5-8 under 35 U.S.C. §102(b), as being anticipated by Ansfield (U.S. Patent No. 5,910,446) (hereinafter the "Ansfield patent").

The Ansfield patent is similar to the Ansfield article and discloses a pretreatment method in a test for the detection of bovine and ovine ruminant proteins in rendered animal materials in which gelatin is removed from the test sample by ammonium sulfate precipitation and proteins are concentrated prior to immunoassay. Applicants respectfully submit that the amendments to the Claims overcome the rejection.

As mentioned above, Claim 1 has been amended to specify that the sample is animal feed or a component thereof, that the unbound ligand is removed from the complex, and that the amount of rendered animal byproduct detected is about 0.005% to about 0.5% by weight of the animal feed sample. The sensitivity of the present method allows for the detection of low amounts of animal byproduct in an animal feed sample without need for gelatin removal or protein concentration, as taught by the Ansfield patent. Accordingly, Applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §102(b) and request withdrawal thereof.

In the September 10, 2004 Non-Final Office Action, the Examiner rejected Claims 1, 8, 9 and 13 under 35 U.S.C. §102(a), as being anticipated by Chen *et al.*, (Meat Science 2002) (hereinafter "Chen *et al*"). Applicants respectfully submit that the amendments to the Claims overcome the rejection.

As mentioned above, Claim 1 has been amended to specify that the sample is animal feed or a component thereof, that the unbound ligand is removed from the complex, and that the amount of rendered animal byproduct detected is about 0.005% to about 0.5% by weight of the animal feed sample.

Chen *et al.* teach a method for detecting rendered muscle tissue in animal feedstuff and disclose that feed samples were mixed by weight with various percentage of meat meals of individual species (see page 407, last paragraph, and footnote C presented in Table 2, Table 3, and Table 4 of Chen *et al.* results). The weight percentage meat meal ranges utilized by Chen *et al.*, are 1%, 5%, 25% and 50%. Applicants respectfully submit that these ranges are outside the limitation recited in amended Claim 1, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight. Support may be found on, at least, page 21, lines 4-22, of the instant application regarding the amount of rendered animal product that can be detected using the applicants highly sensitive method. In view of the improved sensitivity demonstrated by the instant application, applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §102(b) and request withdrawal thereof.

Claim rejections 35 U.S.C. §103 (a)

In the September 10, 2004 Non-Final Office Action, the Examiner rejected Claims 1, 6-10, 12 and 15 under 35 U.S.C. §103(a) as being unpatentable over Schmerr *et al.*, U.S. Patent No. 6,150,172, in view of Hamilton (FAO presentation, Bangkok, April 29-May 3, 2002). The Examiner stated that Schmerr *et al.* disclose methods for selectively detecting protein from numerous sample forms (e.g. bone meal, animal feed, tissue) using immunoassays, but fail to teach that the animal byproduct is rendered, but that Hamilton disclose rendering animal byproducts. The Examiner concluded it would be obvious to one skilled in the art to incorporate a rendering process such as that taught by Hamilton into the method of Schmerr *et al.* to produce an aseptic protein product that is free of potential biohazards and environmental threats. Applicants respectfully submit that the amendments to the Claims overcome the rejection.

As mentioned above with regard to the rejections under 35 U.S.C. §102, Claim 1 has been amended to specify that the sample is animal feed or a component thereof, that the

unbound ligand is removed from the complex, and that the amount of rendered animal byproduct detected is about 0.005% to about 0.5% by weight of the animal feed sample.

Applicants respectfully submit that the deficiencies of Schmerr *et al.* are not cured by Hamilton, because Hamilton fails to disclose, teach or suggest a method for detecting rendered animal byproducts in animal feed. In addition, neither Hamilton or Schmerr *et al.* disclose, teach or suggest a method for detecting of rendered animal byproducts, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.5% by weight. Indeed, Hamilton states, "detection limits and validation procedures are being completed for these technologies" (see page 7, paragraph beginning "a number of governmental agencies").

Therefore, applicants respectfully submit that the detect limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Hamilton and Schmerr *et al.* Accordingly, applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

In the September 10, 2004, Non-Final Office Action the Examiner rejected Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,910,445 to Ansfield in view of U.S. Patent No. 3,654,090 to Schuurs *et al.* and further in view of U.S. Patent No. 5,437,981 to Deger *et al.* Applicants respectfully submit that the amendments to the Claims overcome the rejection.

Claim 3 depends from amended Claim 1 and contains all the limitations thereof. Claim 3 further specifies that the sample is combined with both the ligand (having a detectable label) and an analyte analog that is bound to a solid phase, and that the detectable ligand has a binding affinity for the analyte analog.

Schuurs *et al.* disclose a test system composed of antigen, labeled antibody and immobilized antigen. Deger *et al.* disclose competitive immunoassays to determine an

analyte of interest using an immobilized analog. The Examiner concluded it would be obvious to one skilled in the art to incorporate the testing method of Schuurs *et al.* into the method of Ansfield and that it would be obvious to one skilled in the art to substitute the immobilized analog as taught by Deger *et al.* for the immobilized antigen of Ansfield.

Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(b) rejection of the Ansfield patent apply to this rejection and are repeated here. In addition, the Ansfield patent fails to teach an analyte analog bound to at least one location on a solid phase, wherein the ligand has a binding affinity for the analyte analog. The Examiner stated Deger *et al.* disclose competitive immunoassays using an immobilized analog. However, Deger *et al* fails to disclose, teach or suggest a method for detecting rendered animal byproducts in animal feed. Furthermore, Deger *et al.* fails to teach or disclose the highly sensitive animal byproduct detection method claimed in amended Claim 1. Furthermore, the deficiencies of both Ansfield and Deger *et al.* are not resolved by Schuurs *et al.* who fail to teach detection of rendered animal byproducts at the claimed low detection limits. Accordingly, Applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

In the September 10, 2004 Non-Final Office Action, the Examiner rejected Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over the Ansfield patent in view of U.S. Patent No. 5,571,682 to Jacobs *et al.* and U.S. Patent No. 6,617,116 to Guan *et al.* Applicants respectfully submit that the amendments to the Claims overcome the rejection.

Claim 4 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 4 specifies that the sample is combined with both the ligand and a detectable analyte analog, and that the ligand is bound to a solid phase and has binding affinity for the detectable analyte analog.

The Examiner stated that Jacobs *et al.* disclose a competitive immunoassay having a labeled analog and that Guan *et al.* disclose a competitive immunoassay having a

binding partner immobilized on a solid support. The Examiner concluded it would be obvious to one skilled in the art to incorporate the competitive immunoassays taught by Jacobs *et al.* and Guan *et al.* into the method of Ansfield to arrive at the claimed method.

Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(b) rejection of the Ansfield patent apply to this rejection and are repeated here. The Examiner stated it would be obvious to one skilled in the art to incorporate the competitive immunoassay of Guan *et al.* into the method of Ansfield to provide a quantitative measure of analyte concentration. However, Guan *et al* fails to disclose, teach or suggest a method for detecting rendered animal byproducts in animal feed. Furthermore, Guan *et al.* fails to teach or disclose a method capable of detecting a concentration of rendered animal byproduct of about 0.005 % to about 0.5% by weight. The deficiencies of both Ansfield and Guan *et al.* are not resolved by Jacobs *et al.* who fails to teach a method for detecting rendered animal byproducts. Furthermore, Jacobs *et al.* fails to suggest or disclose the recited limitations regarding detection of specific concentrations of rendered animal byproducts. Accordingly, applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

In the September 10, 2004 Non-Final Office Action, the Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Schmerr *et al.* in view of Hamilton and further in view of Ligt *et al.* (2004/0043107) (hereinafter "Ligt *et al*"). Applicants respectfully submit that the amendments to the Claims overcome the rejection.

Claim 11 depends from Claim 1 and contains all the limitations thereof. Claim 11 further defines the analyte as chondroitin sulfate, aggrecan, osteocalcin, hyaluronic acid or Type II collagen.

The Examiner stated that Ligt *et al.* disclose the presence of chondroitin sulfate in animal byproducts and that the byproducts can be analyzed. The Examiner

concluded it would be obvious to one skilled in the art to detect chondroitin sulfate with the modified method of Schmerr *et al.*

Applicants respectfully submit that the arguments presented above in response to the 35 U.S.C. §102(b) rejection of the Ansfield patent and the comments presented above in response to the 35 U.S.C. §103(a) rejection of Schmerr *et al.* and Hamilton apply to this rejection and are repeated here. The Examiner stated it would be obvious to one skilled in the art to detect chondroitin sulfate with the modified method of Schmerr *et al.* However, Ligt *et al* fails to disclose, teach or suggest a method for detecting rendered animal byproducts. Furthermore, Ligt *et al.* fails to teach or disclose detection of rendered animal byproducts at a concentration of about 0.005 % to about 0.5% by weight. Therefore, the deficiencies of both Schmerr *et al.* and Hamilton are not resolved by Ligt *et al.* Accordingly, applicants respectfully submit they have overcome the Examiner's rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

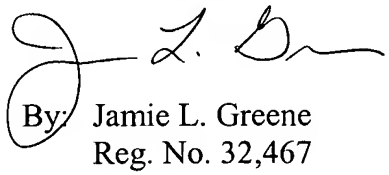
CONCLUSION

Applicants respectfully submit this is a complete response to the Non-Final Office Action dated September 10, 2004, and that the pending claims are definite, novel and non-obvious. Accordingly, Applicants respectfully request allowance of these claims.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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